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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/809,621	06/02/1997	NOBUTAKA IDA	599-158P	7804

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/809,621	IDA ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *PTO-03-4093, PTO-03-4099-*.

DETAILED ACTION

1. Claim 13-17 and 20-24 are pending and under consideration.

2. After review and reconsideration, the finality of the Office action, mailed July 19, 2002 is withdrawn.

3. Sections of Title 35, US Code not found in this action can be found in a prior action.

4. Claims 15, 17 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 24 recite "bone metastasis from mammary carcinoma, lung cancer, prostate cancer, thyroid gland carcinoma, renal cancer, colon cancer, cancer of the digestive tract, and cancer of the esophagus". It is unclear if the limitation of "bone metastasis" is to be applied to all the listed cancers, or if "bone metastasis" applied only to mammary carcinoma.

The recitation of "hormonal disorder" in claim 15 lacks antecedent basis in claim 14.

5. Claims 13, 17, 20 and 22-24 are rejected under 102(b) as being anticipated by Hasse et al (Tumor Diagnostic & Therapy, 1988, Vol. 9, pp. 96-99, cited in a previous action) as evidenced by the attached translation (PTO 03-4093).

Claim 13 is drawn to a method for treating a patient having an osteoclast related bone disorder comprising administering an effective amount of IFN-beta or an IFN-beta inducer to reinstate bone volume of the patient; wherein the bone disorder results from a disturbance between the relative balance of bone resorption and bone formation. Claim 17 embodies the method of claim 13, wherein the osteoclast-related bone disorder is tumor-related and selected from the group consisting of multiple myeloma, bone metastasis from mammary carcinoma, lung cancer, thyroid gland carcinoma, renal cancer, colon cancer, cancer of the digestive tract and cancer of the esophagus.

Claim 20 is drawn to a method for treating a patient having an osteoclast related bone disorder comprising administering a medicament to the patient, wherein the medicament

comprises an amount of an active ingredient that is effective for reinstating bone volume and wherein the active ingredient is selected from the group consisting of IFN-beta and an IFN-beta inducer.

Claim 22 is drawn to a method for treating a patient having an osteoclast related bone disorder characterized by osteolysis, said method comprising administering an effective amount of IFN-beta or an IFN-beta inducer to inhibit osteoclast formation.

Claim 23 is drawn to a method for treating a patient having an osteoclast related bone disorder characterized by osteolysis, said method comprising administering a medicament to the patient, wherein the medicament comprises an amount of an active ingredient that is effective in inhibiting osteoclast formation, and wherein the active ingredient is selected from the group consisting of IFN-beta and IFN-beta inducer.

Claim 24 is drawn to a method for treating a patient having an osteoclast related bone disorder comprising administering an effective amount of IFN-beta or an IFN-beta inducer to inhibit osteoclast formation, wherein the bone disorder results from a disturbance between the relative balance of bone resorption and bone formation and wherein the bone disorder is tumor related and selected fro the group consisting of multiple myeloma, bone metastases from mammary carcinoma, lung cancer, prostate cancer, thyroid gland carcinoma, renal cancer, colon cancer, cancer of the digestive tract, and cancer of the esophagus.

Hasse et al disclose a method for treating patients having osteolytic bone metastases (page 8, lines 7-10 of the translated document) comprising the local injection of IFN-beta (page 9, lines 1-2 and lines 6-8 of the translated doc). Hasse et al disclose that the osteolytic bone metastases were from primary tumors of the breast, prostate, bronchia and kidneys, thus fulfilling the specific embodiments of claims 17 and 24. Hasse et al disclose that administration of the IFN beta induced a complete remission, seven partial remission and six patients were relieved of pain with no change in remission status (Table 4).

6. Claims 13, 17, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Matasuura et al (Japanese Patent 04-77431, published March 11, 1992) as evidenced by the attached translation, PTO 03-4099 and Burkhardt et al (Bull Cancer, 1980, Vol. 67, pp. 291-305).

Matasuura et al disclose a method of treating cancers, specifically renal cancer and multiple myeloma (page 5, lines 8-14 of the translation), comprising administering "Modified Ease Power" (page 3, line21 to page 4, line 23 of the translation) in a dose of 0.3-10 g per day (page 5, lines 15-17 of the translation). Matasuura et al disclose that the action of the drug is not direct, but causes induction of endogenous interferons which react with an antibody against IFN-alpha and IFN-beta (page 6, lines 1-4 of the translation). The abstract of Burkhardt et al discloses that 75 per cent of 428 cases of multiple myeloma exhibited metastases to the bone. Thus, the treatment of patients with multiple myeloma by administration of the interferon inducer disclosed by Matasuura et al would have inherently treated patients with osteolytic bone disorder.

7. Claims 13, 17, 20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Durie et al (J Biol Response Mod, 1985 Vol. 4, pp. 518-24).

Durie et al disclose the treatment of patients with refractory multiple myeloma with poly(I,C)-LC using a 3 times per week intravenous schedule (abstract). Durie et al disclose that multiple myeloma patients included those individuals with progressive disease (page 519, Table 1). Durie et al disclose that significant interferon induction occurred (abstract and page 520, Table 3). Durie et al disclose that patient 2 improved in terms of "bone pain" and patient 1 exhibited correction of hypocalcaemia. One of skill in the art would reasonable conclude that the patient exhibiting bone pain before the treatment has bone metastases. One of skill in the art would conclude that the patient who exhibited correction of hypocalcaemia after treatment also had bone metastases which was causing bone degradation before the treatment. Thus, it would be inherent in the method of Durie et al that the multi-le myeloma patients included those with bone metastases, and the induced interferon reinstated bone volume in said patients.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 13, 14, 16, 17 and 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by McCully (US 5,565,558)

Claim 14 embodies the method of claim 13 wherein the osteoclast related bone disorder is selected from the group consisting of rheumatoid arthritis, Paget's disease, osteoporosis, osteomalacia, osteoarthritis and periodontal disease. Claim 21 embodies the method of claim 20 wherein the osetoclast related bone disorder is postmenopausal osteoporosis.

McCully discloses a method of treating primary and metastatic neoplasms including cancers of the breast, prostate, and kidney (column 6, lines 29-36), as well as and human degenerative diseases associated with aging including but not limited to osteoarthritis, osteoporosis, and rheumatoid arthritis (column 6, lines 53-60) comprising the administration of a composition comprising thioretinaco ozonide and alpha, beta and gamma interferon (column 3, lines 57-60). In examples 2 and 4, McCully discloses that a mouse is given 1,000 IU and 100 IU of IFN-beta. This dosage range falls within the claimed dosage range of claim 16 when extrapolated to the same number of IU/kg or IU/m2 for a human patient. Thus, it would be inherent that the administered interferon beta would reinstate bone volume.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
10/4/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER